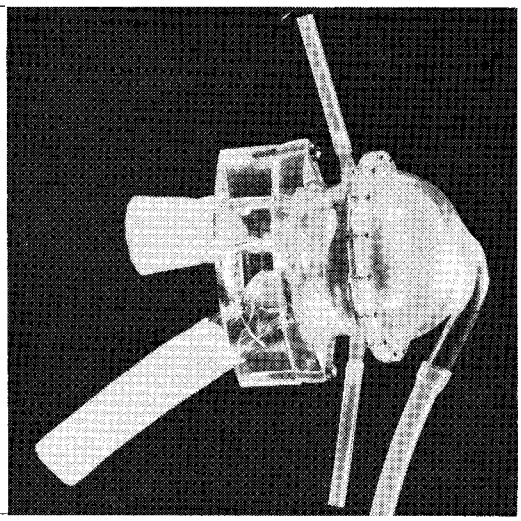
Prospects For And Implications Of The Artificial Heart And Assistive Devices*



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GREAT PROGRESS has been made in recent years toward a better understanding of the cardiovascular system and in the treatment of many of its disorders. The use of artificial arteries fabricated from plastic materials for the replacement of diseased arteries is now commonplace. Similarly, the replacement of diseased and poorly functioning heart valves by artificial valves is being employed daily in most medical centers. Many forms of congenital heart defects—indeed, the majority of them —are now amenable to surgical correction.

Despite these remarkable developments, however, there remains a considerable number of various types of heart disease of both congenital and acquired origins that is not amenable to either medical or surgical correction. Indeed, diseases of the heart and major arteries continue to account for more deaths in this country than do all other diseases combined. The major category accounting for these deaths may be broadly termed myocardial failure, with coronary disease or insufficiency being the most common cause. Although nature's compensatory mechanisms may permit even severely diseased hearts to maintain life for varying periods of time, they ultimately fail, causing death in most of these patients.

The sole known function of the myocardium is to provide the necessary energy or force to pump or to circulate blood. To be sure, this is a critically vital function, but it is also a relatively simple biologic function. Accordingly, the question may be raised concerning the possibility of replacing this pumping function of the heart by means of some mechanical pumping device. The feasibility of such an idea gains credence from the fact that it is now possible to replace heart function completely for relatively short periods, i.e., up to several hours, as demonstrated by the daily use of the artificial heart-lung machine in "open heart" surgery.

Additional support for the feasibility of this concept has been provided in the experimental laboratory, with the use of various types of mechanical pumping devices demonstrating the maintenance of adequate circulation and viability of animals for periods ranging from several days to over a week.

If, therefore, it is possible to provide an effective and completely successful mechanical substitute for the pumping function of the heart for periods ranging from several hours to several days, why should it not be possible to extend this period for months or years?

The obvious answer to this question is that it should be possible. But investigations have shown that as the time is extended during which the various types of mechanical pumping devices now available are used, a number of different problems arise that limit their continued use. And, although the problems are inextricably interrelated, they may be categorized roughly into the following problem areas common to all existing and future mechanical pumping devices: pump design, power source, blood interface, valves, implantation techniques, physiology, and materials.

Pump Design, Power

Blood is a delicate fluid, extremely vulnerable to damage. Subjecting it to any pumping action other than that of the heart itself at once jeopardizes both the cellular components and the dissolved protein fraction of blood. Unhappily, there is a distinct lack of basic information regarding the etiology of blood damage. Few of the standardized blood trauma tests are reliable. During initial periods of investigation, medical scientists implicated turbulence as the primary cause of blood trauma. More recent information, however, indicates that turbulence per se may not figure principally.

The problem then becomes paradoxical: a pump must be designed which minimizes or completely eliminates blood trauma even though there exists no truly reliable measure to indicate when such a design has been achieved. Basically there are two pump designs: pulsatile and nonpulsatile. Which is the better is an unresolved question. Basic research to date justifies favoritism toward a pulsatile design where long-term perfusion is contemplated. Other unresolved areas of design include size, shape, angularity, and material. The net result is a seemingly endless variety of pumps, each with its own merit.

Of the many power coupling modes tested, hydraulic fluid and gas-energized systems emerge as the most popular because they geographically separate the blood-handling parts from the heat-generating portion of the system. Currently, most of the favored artificial hearts derive energy from a power source which both generates and transforms energy extracorporeally. Such systems preclude problems of insufficient power and of heat dissipation within the body.

Achieving implantable power, however, obviously entails the solution of both these inherent problems, with the added restriction of space limitations within the body. Three possible implantable power sources have been identified: electrical, nuclear, and biologic.

Research has proven the feasibility of transporting electrical energy through the chest wall without using transcutaneous wires. This method utilizes the principle of induction between coupled coils, one of which may be implanted beneath the skin to act as a receiver for a transmitting coil which overlies it on the skin surface.

Nuclear energy as a power source offers two possibilities: elecronuclear and thermonuclear. Presently available nuclear batteries lack the energy output to drive an artificial heart (which, with no consideration of power loss, requires six watts). Thermonuclear energy, while it can be contained in a package of implantable size, generates an intolerably high heat level. Its use would necessitate better insulation and heat dissipation than

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is currently possible. Shielding is not a major problem if pure alpha emitters are used in the isotope selection. These emitters, unfortunately, have a rather short half-life.

The prospect of harnessing biologic power is the most attractive and exhilarating possibility. Skeletal muscle would at once appear the most likely source. And, for good reason: (1) its frequency response is within the needed range; (2) larger muscles can handle the power requirements; (3) there is no problem of replenishing power, provided food intake is adequate; and (4) heat dissipation is of no concern since skeletal muscle has a built-in heat exchanger.

Unlike cardiac muscle, however, skeletal muscle requires a long rest period. The possibility exists, nevertheless, that skeletal muscle could be trained for this work and two different groups used alternately to handle the work load.

Blood Interface, Valves

Valves and blood pumps normally are fabricated from nonbiologic materials, usually plastic. The problem of interface between these foreign materials and blood became evident a number of years ago when investigators began searching for blood conduits, blood storage, oxygenators, hemodialysis, and replacement artificial cardiac valves. Identification of the problem has stimulated remarkable basic research, although not sufficient to produce an optimum reliable surface for handling blood. Experiments within the past six months make us more optimistic that a solution to the problem will be found.

In relation to an artificial heart, the problems associated with artificial replacement valves are magnified significantly. Frustrated in their efforts to employ existing artificial valves, many investigators have resigned themselves to designing their own valves—more often than not specifically for their particular type of pump. Cellular trauma bears a near-linear relationship with the types of valves used in the blood pump. Intense effort toward improved valve design may produce a better valve not only for artificial hearts but also for replacement in the biologic heart as well.

Implantation Techniques

The ultimate use and usefulness of an implantable blood pump will relate directly to the ease and speed with which it may be inserted. Present methods of implantation are complicated, tedious, and time-consuming. Problems of insertion, as well as intracorporeal space limitations, will necessarily influence pump design. Even seemingly simple considerations in the area of implantation techniques have taxed everyone's imagination and, to date, without a workable solution.

Physiology

A more comprehensive understanding of basic physiology of the heart is sorely needed. Numerous questions remain outstanding. Does the biologic heart play an active role or is it a totally passive pump whose output is dictated by the peripheral circuit? Certainly its volume output cannot exceed its intake and since it has little, if any, storage capacity, it must pump all blood delivered by the systemic circuit. The biologic heart may have the capacity, however, to demand a greater blood volume by decreasing its systolic residue, thereby increasing the filling pressure gradient.

If so, can this peremptory action be duplicated by a purely passive blood pump? Are the pressure wave forms so fundamental that they must be duplicated exactly? Cardiovascular physiologists are seeking the answers to these and other questions. Their efforts undoubtedly will lead to a better understanding of the biologic cardiovascular system.

Materials

Artificial hearts have been fabricated primarily from plastics, particularly Silastic.® To date, no material has proven entirely satisfactory. Conversely, no specifications for an "optimum material" can be written until we are able accurately to identify all inherent problems. We can, however, prescribe certain general specifications, some of which are obvious: where flexion must occur, for example, the material must have a long flex-life; where there is elongation, it must have elasticity; where contact with blood is encountered, it must have "atraumatic surface properties."

But such generalizations are meaningless to a polymer chemist attempting to produce the "optimum material." By no means, however, do we consider the concept of an "optimum material" to be mythical, and through the interest of engineers and polymer chemists and their demands for precise terminology, we are beginning to emerge from the cloudy environment of nebulous specifications.

It should be apparent from the brief foregoing discussion that development of an implantable artificial blood-pumping device able to sustain human life will be realized only through a multidisciplinary approach undergirded by conscientious investigators and adequate funds. And when it does become a reality, the artificial heart will emerge not as a dramatic breakthrough but as the accumulative precipitate of many a small breakthrough.

Profound Implications

Once available, the artificial heart will entail considerations which will impinge upon the mind and conscience of not only physicians but also philosophers, theologians, sociologists, jurists, and many others. On the one hand we have the tool and on the other, the candidate. Should this life-saving device be made available to every patient, even the hopeless victim of stroke, cancer, or senility? Or, should an unbending and restrictive criterion for use be outlined? When and how does one determine death due to other causes? And, who decides when to terminate the power flow in such cases?

These questions are obvious and already are being argued as a result of the prolongation of life through such artificial devices as respirators and artificial kidneys.

But, if pursued further, the implications of an artificial heart are truly profound. For example, who can fathom the problems thrust upon society if advances in medicine should increase life expectancy to, say, 200 or 300 years? Would not such an occurrence dictate control of birth rate? Would not individual responsibility to society for productivity be increased decades beyond the present retirement age of 65 years? Of course, the implications of an artificial heart—or any other life-sustaining artificial device—can be pursued to an absurd extreme. But certainly it is obvious that definitive guidelines will have to be set.

In the broader scope of treatment of heart disease, the artificial heart must be considered a stopgap measure. The ultimate and desirable measure must be prevention. But until such a time as we have at hand full information concerning disease processes and thus are able to take preventative measures, effort toward development of an artificial heart is justified and must continue. Indeed, even if all facets of heart disease prevention were made available tomorrow, the present generation would require the benefits of a workable artificial heart.

In 1966 well over a half million people in the United States will die of heart disease and a fourth of the adult population will be threatened by its occurrence. In 1962 the sum of direct costs, plus losses of output by members of the labor force due to heart disease, amounted to $22.4 billion, or 4% of the Gross National Product. These are grim facts that cannot be easily ignored. Indeed, they provide our greatest impetus to continue and intensify this research effort. ♥